Q. When you have worked as a consultant for Quantic Regulatory Services, have you done batch record reviews for them or for other companies and other products? 03:17

A. No. And if I could, please, when you say Quantic Regulatory Services, there's -- if I'm not mistaken there's like three entities of Quantic. One is the regulatory services, one Quantic, and there's another one, depending on what the job is covered by. 03:17

So to answer that question accurately, I'm not sure which one we're referring to, which one of those business entities, just to be clear. 03:17

Q. How many companies -- how many other companies that you worked for in the pharmaceutical industry were at one point on consent decree? 03:18

A. As a permanent employee worked for? 03:18

Q. Yeah. 03:18

A. At one point? 03:18

Q. Yeah. 03:18

A. To my knowledge, none of the companies. 03:18

Q. What about in your consulting arrangements? How many of the companies have been on consent decree at some point? 03:18

A. That I know of? 03:18
Q. Yeah. 03:18
A. Two. 03:18
Q. And Wyeth was one. Are you able to tell me who the other one is? 03:18
A. Schering Plough. 03:18
Q. When you were working with those companies regarding consent decrees, did you tell them that a consent decree was because of a repeated and persistent non-compliance with the law? 03:18
A. That was not my function to tell the companies that. So me personally, no. 03:19
Q. Did you believe when you were consulting with them that they were on consent decree because of repeated, persistent non-compliance with the law? 03:19
MR. KERENSKY: Wait a minute. I want to caution you there. 03:19
THE WITNESS: Yeah. 03:19
MR. KERENSKY: We're on the same page. Because you're now asking him to say something, a conclusion he drew based on stuff he knew about while working there and working with them, which may be covered by the 03:19

confidentiality agreements he has. 03:19

THE WITNESS: All I know, if I could, is that these companies all post the consent decree and the letter by quality assurance and management on bulletin boards so everybody can see what it's all about. That's part of the function. 03:19 03:19 03:19 03:20 03:20 03:20

BY MR. MORIARTY: 03:20

Q. I understand that. But do you -- I mean you have said that my client or pharmaceutical companies in general go on consent decree for repeated, persistent non-compliance with the law, and I'm trying to find out whether that is a phrase that you're applying only to Actavis or whether you also apply it to companies that you consult with in the non-litigation world. 03:20 03:20 03:20 03:20 03:20 03:20 03:20 03:20 03:20

A. Again, I'm not -- 03:20

THE VIDEOGRAPHER: Five minutes. 03:20

THE WITNESS: Again, I'm not sure I really understand the gist of the question. I apologize. 03:20 03:20 03:20

BY MR. MORIARTY: 03:21

Q. Okay. At page 8 of your report. 03:21

A. Okay. 03:21

Q. It says: 03:21

"It should be noted in my experience consent decrees are not common and mostly occur when a company has shown repeated and persistent non-compliance with the law." 03:21

Do you see that? 03:21

A. Yes, I do. 03:21

Q. All right. What I'm trying to find out about, Dr. Bliesner, is whether you are just making a comment about my client or whether that is your opinion about pharmaceutical companies and the consent decree generally. 03:21

A. Yes. 03:21

Q. Yes which? 03:21

A. They -- that it takes an awful lot to get a consent decree. It's a progress of numerous 483s, warning letters in most circumstances. Sometimes they go directly to it. There's numerous 483s, warning letters, and then it gets to the point where the agency says we don't have enough resources anymore to manage this. Let's go into an agreement. 03:21 03:22

Q. And have you ever consulted with a pharmaceutical company about a product that was in litigation, product liability litigation? 03:22

A. Consulted specifically about the product 03:22

liability? 03:22
Q. Yeah. 03:22
A. No. 03:22
Q. Does the ANDA for any product, including Digitek, contain the formula for the active ingredients and how they are to be blended? 03:22
A. The formula, yeah. The combination of excipients and active. 03:22
Q. Yes. 03:22
A. In my experience they do contain that. 03:22
Q. And presumably they have to be mixed in appropriate proportions in order to comply with the formula; correct? 03:22
A. They need to follow their manufacturing steps in order to -- to come up with a proper dosage for them, whether it involved mixing or whatever. 03:23
Q. And those steps are approved by the FDA; correct? 03:23
A. Those steps are in the application. If the application is approved and the FDA has found the information in the application acceptable. 03:23
THE VIDEOGRAPHER: We should definitely change tapes. 03:23
The time is 3:26 p.m. We're going off 03:23

the record. 03:23

THE VIDEOGRAPHER: The time is now 03:34

3:37 p.m. We are back on the record. This is 03:34

the beginning of tape six. 03:34

BY MR. MORIARTY: 03:34

Q. Okay. We were asking before the break 03:34

about formulas; okay? Have you seen any 483 or a 03:34

warning letter, any sort of citation or sanction 03:35

by the FDA on Actavis for any problem with the 03:35

actual mixing of the ingredients? In other words, 03:35

using inappropriate proportions of ingredients? 03:35

A. Proportions? 03:35

Q. Yes. 03:35

A. Not that I recall. 03:35

Q. So you don't have any evidence that any 03:35

Digitek batch started with too much active 03:35

pharmaceutical raw ingredient? 03:35

A. I don't have any evidence. 03:35

Q. You are aware that Actavis tests every 03:36

batch at the blend stage. 03:36

A. Every batch at the blend stage? 03:36

Q. Yeah. 03:36

A. I don't have information that I've seen 03:36

that confirms or denies that. 03:36

Q. Okay. 03:36

In your work in the pharmaceutical industry -- not in your consulting work -- how much contact did you have with blend uniformity sampling or testing? 03:36

A. Testing. 03:36

Q. So not sampling? 03:36

A. No. 03:36

Q. Not the core sampling? 03:36

A. No. 03:36

Q. But you did have some with testing? 03:36

A. Yes. 03:36

Q. And typically when a company does blend sampling from a dry blend batch, how many core samples do they take and submit to a QC lab for analysis? 03:36

A. That varies. It's not a set thing. 03:37

Q. From your reading -- 03:37

A. And it's always a battle. 03:37

Q. Why is it a battle? 03:37

A. Because the lab always wants less samples and the validation people want more samples, and they go back and forth to try to determine number of samples to be sent to be analyzed. It's a very big challenge. 03:37

Q. Why does the lab want less samples? 03:37

A. Because usually you're doing their release testing on top of process validation, so it's doubling their workload. 03:37

Q. From your reading in pharmaceutical publications over time, have you found that blend uniformity sampling and testing in general is a controversial subject? 03:37

A. Controversial? 03:37

Q. Yes, sir. 03:37

A. I wouldn't use the word controversial. 03:38

Q. Have there been efforts by pharmaceutical companies to have the FDA eliminate the requirement of blend uniformity sampling because it's notoriously difficult to do and control well? 03:38

A. I know that Actavis in some of their documentation make reference to try to stop blend uniformity testing. 03:38

Q. Do you know about any other company? 03:38

A. Specifically that I've been involved with? 03:38

Q. Actually I mean generally. 03:38

A. Generally. 03:38

Q. Your general knowledge of the industry. 03:38

A. Blend uniformity as I said is always a 03:38

challenge anyway, so... 03:38

Q. Okay. So can you point to me any 03:38

document where the FDA cited or warned the company 03:38

because an actual batch had out-of-specification 03:38

blend uniformity samples? 03:39

A. The FDA cited? 03:39

Q. Yeah, which then went on uncorrected or 03:39

the tests weren't repeated? 03:39

A. It would -- there are references to 03:39

blend -- if I'm not mistaken there are references 03:39

in 483s and/or potentially EIRs with respect to 03:39

blend if I recall. I'd have to go back and dig 03:39

through and look at it specifically. 03:39

Q. Yeah, but do you know whether that had 03:39

to do with the way they investigated and the 03:39

number of samples -- and the number of samples 03:39

they took or whether it was actual blend 03:39

uniformity failures that were not addressed? 03:39

A. As I said, I would have to go back and 03:39

look specifically as what those discussions were. 03:39

It's been a while. 03:40

Q. Is it important to your opinions in this 03:40

case? 03:40

A. I think so, yes. 03:40

Q. Is there a difference between an actual 03:40

blend uniformity failure that might require batch rejection and some technical need to either investigate differently or the way you did your backup testing? 03:40

A. I don't understand that question. 03:40

Q. All right. It wasn't a very good question. You'll find that late in the day with this stuff, you can mess up the questions. 03:40

A. This is hard work. 03:40

Q. All right. So let's just assume that a company takes ten core samples from various sections of the blender for the blend uniformity sampling; okay? 03:40

A. Yes. 03:40

Q. Now, let's assume that one of the ten is out of specification. 03:40

A. Yes. 03:41

Q. Okay. 03:41

A. Uh-huh. 03:41

Q. A company is entitled to retest either a portion of that sample or take a new sample from that part of the blender, aren't they? 03:41

A. Retest, resample. You have to be very careful on how you're defining those terms. 03:41

Q. Well, let's go back. Let's assume that 03:41

the core sampling device, the sample thief. 03:41
A. Yes. 03:41
Q. Let's just assume for the sake of 03:41
argument -- 03:41
A. Uh-huh. 03:41
Q. -- that it is the length and diameter of 03:41
my pen -- 03:41
A. Okay. 03:41
Q. -- that I'm holding in front of the 03:41
camera; okay? 03:41
A. Uh-huh. 03:41
Q. So you put that in and you fill it with 03:41
blend. Actually, I think the sampling techniques 03:41
require a lot less than the length and diameter of 03:41
my pen. But let's assume you have enough to test, 03:42
okay, and you have some left over; all right? 03:42
A. Yes. 03:42
Q. Is there any FDA reg -- GMP or 03:42
otherwise -- that if the first test on the sample 03:42
is out of spec, it says that you have to reject 03:42
the batch and that you cannot test the remaining 03:42
sample in this sample field? 03:42
A. Well, there's a whole process that gets 03:42
to that, the resampling stage. If you have a 03:42
failure of an analysis in the laboratory, it 03:42

requires a laboratory investigation to determine whether that result is valid or not. 03:42

Q. Okay. But the question is, is there a FDA reg that prevents you from testing more of the sample that you took? 03:42

A. Not to my knowledge. 03:42

Q. Is there an FDA reg that prevents you from resampling from that part of the blender and then testing that material? 03:42

A. Not to my knowledge. 03:43

Q. Is there any FDA reg -- including GMP regs -- that require companies to reject a batch based on one out of say ten blend uniformity tests? 03:43

A. Regulations? 03:43

Q. Yeah. 03:43

A. Not to my knowledge. 03:43

Q. So if we were to look at the Actavis batch records and find that, for example, that on initial testing, one sample was out of spec, and the company did an investigation and retested and it was not out of spec on retesting, you're not saying that Actavis had to reject that batch for blend uniformity failure, are you? Just answer my question. 03:43

A. Yeah. Say it again, please. These are very difficult issues. 03:44

Q. Sure. 03:44

A. Very difficult issues and they happened frequently. 03:44

Q. All right. So if you go into the records -- 03:44

A. Yes. 03:44

Q. -- you've had, all this paper, and you find that there was a blend uniformity out of spec result -- 03:44

A. Yes. 03:44

Q. -- for one out of ten samples for a particular batch; okay? 03:44

A. Uh-huh. 03:44

Q. Are you with me so far? 03:44

A. I am. 03:44

Q. And they retested it and it was within the specs and hence passed blend uniformity and was sent on for packaging, is it your opinion that that one out of spec result would have -- would have required rejection of the batch? 03:44

A. Perhaps. If you have a failure like this and you can't find a root cause for it and your investigation doesn't lead to anything, then 03:45

there are some very serious discussions that need to be made with respect to the disposition of that batch. 03:45

Q. All right. But that doesn't automatically require a batch -- 03:45

A. Automatically -- 03:45

Q. -- rejection. 03:45

A. Automatically, knee jerk, no. 03:45

Q. You're supposed to -- the regs require that you do an investigation; correct? 03:45

A. Specifically I'd have to go back and look at the GMPs to see where they say -- excuse me -- say exactly that you must reject. It is expected in the industry that manufacturing investigations are investigated very thoroughly to determine a root cause. 03:45

Q. Okay. And it could be a manufacturing investigation or a lab investigation under these circumstances we're talking about with blend uniformity, couldn't it? 03:46

A. Yes, the lab in most cases is involved even if it is a manufacturing investigation because the laboratory people have a tendency to be some of the more technically trained folks on the staff and they usually are cross-functional 03:46

teams when these types of issues come up. So you can solve the problem with the best information we have. 03:46

Q. So if there is a circumstance in the documents where this has occurred, FDA could go back and say we don't like the way you conducted the investigation and write up an observation and a 483 just about the way the investigation was done; correct? 03:46

A. That is correct. 03:46

Q. But not necessarily go the next step and say you should have rejected the batch. 03:46

A. It could; it could not. 03:47

Q. Right. 03:47

A. Uh-huh. 03:47

Q. But it doesn't follow as night does day that they would say you have to reject the batch. 03:47

A. Not to sound redundant, these are very complex issues and each one is separate and unique. 03:47

Q. And each one needs to be studied in this much detail; correct? 03:47

A. Absolutely. 03:47

Q. Now sitting here off the top of your head, without having to dive into these boxes, do 03:47

you know exactly what the blend uniformity issues were that FDA addressed in 483s regarding Digitek? 03:47

A. Without going back and diving into my boxes, I can't tell you exactly what happened. 03:47

Q. Do you know off of top of your head whether FDA ever cited, warned, sanctioned Actavis for passing a batch at the blend uniformity stage that FDA says should have been rejected? 03:47

A. There were discussions, if I recall, in EIRs and 483s with respect to blend uniformity. 03:48

Q. That wasn't my question. 03:48

A. Okay. What was your question? 03:48

MR. MORIARTY: Read it back, Phil, please. 03:48

(Whereupon, the testimony was read back by the court reporter, as recorded above) 03:48

THE WITNESS: I can't off top of my head answer that question. 03:48

BY MR. MORIARTY: 03:48

Q. If a pharmaceutical -- let me withdraw that because I talked with you about that before. 03:48

Have you been shown any information whatsoever to indicate that there was an outbreak of Digoxin toxicity in 2006, 2007, or 2008 at any hospital, nursing home, clinic, or outpatient facility in 03:49

the United States? 03:49
A. When you say "outbreak" you mean? 03:49
Q. Up-tick, increase. 03:49
A. I know there's a document in here that 03:49
looks at adverse events and the numbers of them, 03:49
but that's all -- I would have to look at that and 03:49
speak to it. 03:49
Q. And you're not a pharmacovigilance 03:49
expert? 03:49
A. I am not. 03:49
Q. And do you know even know whether 03:49
adverse event reporting is considered by FDA to be 03:49
a causal connection? 03:49
A. Causal connection? 03:50
Q. Whether adverse event reporting is 03:50
necessarily caused by adulterated or out of spec 03:50
product? 03:50
A. It can be a flag, obviously. 03:50
Q. I understand that. 03:50
A. Yeah. 03:50
Q. For them to look that? 03:50
A. Yes. 03:50
Q. But if it did, it's not somebody makes 03:50
an adverse event report and you automatically 03:50
conclude that you have a problem with your 03:50

manufacturing; right? Am I right about that? 03:50
A. Say that again, please. And it's late 03:50
in the day for me, too, so... 03:50
Q. Okay. Let's take a step back. These 03:50
lawyers hired a pharmacovigilance expert. 03:50
A. Okay. 03:50
Q. From Philadelphia, Karen Frank. 03:50
A. Okay. 03:50
Q. Would you defer to her on these 03:50
pharmacovigilance issues? 03:50
A. Yes. 03:50
Q. So, what I was trying to -- oh, never 03:51
mind. Other than what you said, about AERs, which 03:51
you would defer to somebody else, you haven't seen 03:51
evidence in medical literature or scientific 03:51
publications that there was some increase in 03:51
Digoxin toxicity in two or three years before this 03:51
recall, have you? 03:51
A. I have not specifically gone out and 03:51
looked for that in the literature. 03:51
Q. Have you talked to any cardiologists 03:51
about this case, informally or otherwise? 03:51
A. In doctor-client privilege, I had 03:51
discussion. 03:51
MR. KERENSKY: That's interesting, isn't 03:51

it? 03:51

MR. MORIARTY: Yeah, this will be fun. 03:51

BY MR. MORIARTY: 03:51

Q. Do you take Digoxin? 03:51

A. I do not. 03:51

Q. And presumably you were not consulting a doctor about a prescription for yourself -- 03:51

A. No. 03:51

Q. -- when you were talking about Digoxin; correct? 03:51

A. That's correct. 03:51

Q. And was the party to this conversation your primary care physician? 03:52

A. Yes. 03:52

Q. Is he or she a cardiologist? 03:52

A. Yes. 03:52

Q. Okay. But the discussion had to do with Digitek or Digoxin? 03:52

A. Where do we really fall on this? I'm not really comfortable talking about what I talked about with my doctor regarding this. 03:52

Q. Well, if you were talking about your own medical care, then it's privileged and I'm going somewhere else. If you were talking hey, buddy, I'm consulting on this Digitek litigation. What 03:52

do you know about it, what do you think about it, that's not privileged because you weren't talking to him about your own medical -- 03:52

A. I was not specifically asking him about that. 03:52

MR. KERENSKY: Yeah, we don't necessarily -- I don't necessary agree with your characterization of where the line is on what's privileged. And so there's an argument just like he made and I made that the line is here. There's an argument that everything you talk to your doctor about in your doctor's office is privileged; okay? I'm sure that's what the doctor would say under HIPAA. 03:52 03:53

So it's your call whether or not you want to share this with him. 03:53

THE WITNESS: I prefer not to talk about it. 03:53

MR. KERENSKY: And if you guys want to press it, just take it up with the Judge; okay. 03:53

BY MR. MORIARTY: 03:53

Q. Did you show this doctor any documents from the Digitek litigation? 03:53

A. I didn't think we were going to talk 03:53

about this anymore. 03:53
Q. That's a different question. 03:53
A. No. 03:53
Q. Dr. Bliesner, you are aware that Digitek has a theoretical batch yield, are you not? 03:54
A. Yes. 03:54
Q. So if you put the ingredients in appropriately, if you're making .125 Digitek, you should get 4.8 million Digitek tablets or thereabouts; right? 03:54
A. Say that again. 03:54
Q. If you put the appropriate ingredients into according to the formula, you should get 4.8 million tablets before waste, sampling, retained samples, things of nature? 03:54
A. Without having gone back to look at it, I'll trust you have the number and that's accurate. 03:54
Q. Is there always at least some loss or waste in the manufacturing process? 03:54
A. Invariably, yes. 03:55
Q. If a company consistently made double-sized tablets, would the actual batch production outcomes come close to the theoretical yield numbers? 03:55

A. I'm sorry. Say that again. 03:55
Q. If the company consistently made 03:55
double-sized the tablets -- 03:55
A. Uh-huh 03:55
Q. -- would the actual batch production 03:55
numbers come close to the theoretical yield 03:55
numbers? 03:55
A. I don't know. I would have to think 03:55
about that a little more. I don't think there's a 03:55
one-to-one correlation between theoretical yield 03:55
and this potential double-thick tablet. I 03:55
don't -- I would not speak definitively on that. 03:55
I have to really think about it. 03:55
Q. Well, if you made an entire batch 03:55
somehow of double-thick tablets -- 03:55
A. Uh-huh. 03:55
Q. -- are you going to get 4.8 million? 03:55
A. An entire batch? 03:55
Q. Yes, sir. 03:56
A. I would say that's probably not going to 03:56
get 4.8 million. 03:56
Q. If you made one quarter of the tablets 03:56
double thick, you wouldn't get close to 4.8 03:56
million either, would you? 03:56
A. No, I think you have to be very careful 03:56

in trying to make those kinds of assessments because we don't know double-thick tablet again was ever testified. So we don't know what the weight is, we don't know what the total excipients, we don't know what the active is. We have no idea of being able to just off the top of your head, back of envelope calculation say how much it would be up short. I just don't think it's possible. 03:56

Q. Did you ever see any evidence in any company documents to indicate that there was some adverse trend in Digitek yield production? 03:56

A. If I recall, early on there was some discussions -- and it may have been with the FDA -- with respect to yield difficulties. 03:57

Q. What years are you talking about? 03:57

A. I don't know. Again, I'd have to go back and dig through the documents and look at them. 03:57

Q. Did any of that occur in 2005, 6, 7 or 8? 03:57

A. I can't tell that you without going back and looking through them. 03:57

Q. Why, in general, do you think some problem that occurred in 1995, for example, is 03:57

evidence that defective Digitek got into the hands of consumers in 2007 or 2008? 03:57

A. It's actually fairly straightforward. As I said in the report, primary difficulties in situations like this, in my experience and my opinion is lack of leadership. It's the number one. The people who were running the company back then when they had problems with first consent decree up until just before the second consent decree are same people who are running people the same people on regulatory force, the same people in quality, the same people that caused all the initial problems were still there. 03:57 03:57 03:57 03:57 03:57 03:58 03:58 03:58 03:58 03:58 03:58

Q. Is that some scientific theory? 03:58

A. It's a -- it's a statement of fact. 03:58

Q. So, in other words essentially what you're saying is because they were sloppy in '95 means they must have been sloppy in '06 and '07? 03:58 03:58 03:58

A. I think the information that I've reviewed pretty consistently shows they got out from underneath the consent decree, they became recidivistic, and they moved right back into another situation with many of these same problems. That reflects on leadership. 03:58 03:58 03:58 03:58 03:58 03:58 03:58

Q. But not one thing that you just told me 03:58

is scientific evidence of defective tablets getting into the hands of consumers. Are you talking about FDA documents? 03:58 03:59 03:59

A. It's a failure of quality which impacts the quality of the product going out the door. 03:59 03:59

Q. Well, if the quality was so bad from '95 through 2008 -- let's just pick that period of time, those 13 years -- shouldn't there be some evidence of defective Digitek getting into the hands of consumers? 03:59 03:59 03:59 03:59 03:59

A. There are evidence. The pharmacy individuals. 03:59 03:59

Q. One tablet out of a billion. Got anything else? 03:59 03:59

A. As far as scientific data specifically showing that it was in the hands of the individual? 03:59 03:59 03:59

Q. Yes. 03:59

A. There was nothing in the record. However, you know, you have a billion tablets let's say. It's the number everybody's throwing around. Start doing the math, say it's .00001 percent, you know, how many tablets is that? There's a lot of tablets in the market and you may never seen it. They could hurt the people. 03:59 03:59 03:59 03:59 03:59 03:59 04:00

Q. You may never see it; right? 04:00
A. That exists. 04:00
Q. Okay. So the one tablet that was found 04:00
in 2003 or 4 was found by a pharmacist, wasn't it? 04:00
A. I believe that's what we said earlier. 04:00
Q. Have you ever worked in a pharmacy? 04:00
A. I have not. 04:00
Q. Do you have any expertise in pharmacy? 04:00
A. A pharmacist? No, sir. 04:00
Q. Well, if the one tablet we know about in 04:00
2004 could be detected by a pharmacist, isn't it 04:00
reasonable to conclude that other extra-thick 04:00
tablets, if they existed, would be detected by 04:00
pharmacists? 04:00
A. Could be. 04:00
Q. But that is the only one you know 04:00
about. 04:00
A. Those two specific instances and the 04:00
documents I've reviewed. 04:00
Q. Let's talk about sampling rates. Are 04:01
you an expert in the design and implementation of 04:01
sampling plans for in-process pharmaceutical 04:01
testing? 04:01
A. I am not. 04:01
Q. Do you at least know that in-process 04:01

sampling plans are FDA approved? 04:01

A. In the application? Is that what you're 04:01

asking? 04:01

Q. Initially in the AMDA; correct. 04:01

A. I'm not sure whether that specific 04:02

sample plan exists in the AMDA. I would have to 04:02

take a look. I know procedures, internal guidance 04:02

and SOPs companies have with respect to sampling, 04:02

and they are pretty unique. 04:02

Q. Are you aware of any 483 or warning 04:02

letter comment at any point from 2005 to 2008, 04:02

which observed problems with Digitek in-process 04:02

sampling, meaning weight, thickness? 04:02

A. Specific physical testing? 04:02

Q. Hardness. 04:02

A. I have not seen any that I recall. 04:02

Q. And I assume that this sort of 04:02

in-process testing in general is supposed to tell 04:02

you something about the consistency of the tablets 04:02

that are coming off the presses; is that right? 04:02

A. At various stages within the process. 04:03

It's not like you just grab a hold and spot. 04:03

In-process testing involves -- as you said, you've 04:03

already said -- blend uniformity at certain steps 04:03

along the way. 04:03

Q. Well, right now I'm just talking about the thickness, hardness, the color, weight. 04:03

A. That's kind of -- as far as in-process goes? 04:03

Q. Yeah. 04:03

A. I'm not -- okay, I don't recall what their in-process tests were for this particular product. 04:03

Q. But you've not seen any FDA citations or warning implicating those processes? 04:03

A. Not that I recall. 04:03

Q. But I am correct that what you do in there when QA comes in and the actual press operator is checking, is to see at least visually and by measurement whether the tablets are consistent in size, weight, hardness, things of that nature; correct? 04:03

A. It's a limited testing in process to see where you are, how it's progressing. 04:03

Q. But that's what it's designed to tell you, limited as it may be? 04:04

A. Yes. 04:04

Q. So let's talk about finished product testing, which is within your bailiwick. Did the AMDA have description of the methods that would be 04:04

used to assay content uniformity and dissolution tests Digitek at the finished product stage? 04:04

A. Not specifically looking at the ANDA. I remember -- I'm pretty sure the methods would be in there. They should be. 04:04

Q. Are they also -- 04:05

A. I need to interject here that I'm not sure that I had an opportunity to review all of the sections of the ANDA when they were up on the website for me. So I got to be careful here. I'm not sure if I had the whole package 04:05

Q. Have you looked at the method operating instructions or anything else regarding the testing methods? 04:05

A. I have looked at some methods. I would have to go back and look and see what specific methods there were. 04:05

Q. I didn't see any criticism in your report of Actavis's method for finished process testing Digitek. Am I correct about that? 04:05

A. There is nothing in the report. However, I was not pointed specifically to look at methods in particular. I did not do a wholesale, soup to nuts -- as I normally do -- review of the laboratory control system. 04:05

Q. When you say as you normally do in a lab control system, you mean for a consulting non-litigation project; right? 04:05 04:05 04:06

A. Yes. 04:06

Q. Well, certainly if the Plaintiffs' lawyers were concerned about the finished product methods, they would have probably pointed you in that direction; correct? 04:06 04:06 04:06

A. I wouldn't make that conclusion. We ran out of time as much as anything else. 04:06 04:06

Q. And excuse me if I asked you this before, but you have not seen in any 483 or warning letter any sort of statement by FDA that Actavis's finished product testing of Digitek was in some way deficient; correct? 04:06 04:06 04:06 04:06

A. No, we did not talk about that. And I vaguely recall that there are discussions with respect to analytical methods not being sufficient for their intended use and/or validated in some of these documents that the FDA has generated. I have to go back and look at them. 04:06 04:06 04:06 04:06 04:07

Q. For Digitek? 04:07

A. I can't say for certain, but I know that there are discussions through 483s and warnings letters with respect to the laboratory records and 04:07 04:07 04:07

methods. 04:07

Q. Did FDA ever say that there was a batch that had out-of-spec results that should have been rejected because the methods or even the investigations were inadequate? 04:07

A. Methods? 04:07

Q. Or investigations? 04:07

A. Or investigations. Again, I'd have to go back and look at it because there are discussions with respect to methods, methods validation and testing that come up throughout these FDA documents. 04:07

Q. But my question is very specific. 04:07

A. Okay. 04:08

Q. Do you remember any statements in any FDA documents to the effect that Digitek batches should have been rejected because analytical methods were inadequate or investigations were inadequate? 04:08

A. I can't say that off the top of my head. I really can't. Analytical methodology is invariably one of the observations the FDA makes for companies in trouble. 04:08

Q. Let's go to page 7 of your report. 04:08

MR. KERENSKY: Can we take a stretch 04:09

break after you finish this thing, this little subject? 04:09 04:10

MR. MORIARTY: How long on the tape? 04:10

THE VIDEOGRAPHER: 25 minutes. 04:10

MR. MORIARTY: Yeah. 04:10

BY MR. MORIARTY: 04:10

Q. Okay. Page 7. 04:10

A. Yes. 04:10

Q. It says product recalls. 04:10

A. Yes. 04:10

Q. The first one is in 1990. Was that Digitek? 04:10 04:10

A. I don't know. 04:10

Q. What would you have to look at to figure it out? 04:10 04:10

A. It was just a -- if I recall, it was a business summary that was presented by one of the CEOs and it just said there was a product recall. If I -- I'm pulling this off my memory, which I hesitate to do that. 04:10 04:10 04:10 04:10 04:10

Q. In 1995, Class III? 04:10

A. Uh-huh. 04:10

Q. That's not recalled at the consumer level; correct? 04:10 04:10

A. Uh-huh. 04:10

Q. Is that right? 04:10
A. That's correct. 04:10
Q. Because of incorrect package insert. 04:10
Which is, in your words, a failure of packaging 04:11
and labeling portions of the cGMPs; correct? 04:11
A. Correct. 04:11
Q. Was it Digitek? 04:11
A. I'd have to look. That may be one of 04:11
those things as well that was just stated as. 04:11
Q. And certainly FDA or Amide at the time 04:11
didn't consider this as a patient safety issue 04:11
because it was a Class III recall; correct? 04:11
A. Correct. An immediate threat. 04:11
Q. And the 2008 August total product 04:11
recall, which is the last one that you list -- 04:11
A. Yes. 04:11
Q. -- that was a Class III recall, wasn't 04:11
it? 04:11
A. I don't recall. 04:11
Q. Well, that's important to know, isn't 04:11
it? 04:11
A. Let's take a look. 04:11
MR. MORIARTY: Let me make sure we're on 04:12
the same page. 04:12
THE WITNESS: Okay. 04:12

BY MR. MORIARTY: 04:12

Q. Was the 2008 August recall to the consumer level? 04:12

A. What page were we on again back in the document? 04:12

Q. Seven. 04:12

A. Seven? 04:12

Q. But you don't have a reference? 04:12

A. Seven, the August recall? 04:12

Q. Yeah, I guess you would be looking at A49, A55, 63. That's what your table says 04:12

A. 25 April, 2008? 04:13

Q. No, sir. August 2008. It would be your reference A63. 04:13

A. 63. 04:13

Q. And on page 61 of your report you say that it was recalled at the retail level. 04:13

A. Where in the report? 04:13

Q. Page 61. 04:13

A. Yeah. 61, reference A63? 04:13

Q. Yes, sir. 04:14

A. Recall from press release, FDA website "Actavis auto announces voluntary recall at retail level of all drugs manufactured." Then that's what that was. 04:14

Q. All right. So even though FDA may have been concerned about good manufacturing practice violations in 2008 or 2007, there was not a recall of these other products to the consumer level; correct? 04:14

A. According to that. 04:14

MR. MORIARTY: Okay. You want to take a stretch break? Let's go off the record for -- 04:14

MR. KERENSKY: Thank you for remembering. 04:15

MR. MORIARTY: For five minutes. 04:15

THE VIDEOGRAPHER: The time is 4:17 p.m. We're going off the record. 04:15

THE VIDEOGRAPHER: The time is now 4:28 p.m. We are back on the record. 04:25

(Whereupon, Exhibit 106 was marked for identification) 04:26

BY MR. MORIARTY: 04:26

Q. Okay. I'm going to show you what has been marked as Exhibit 106; okay? This is a notice of your deposition for today; all right? 04:26

A. Okay. 04:26

Q. Have you seen that before? 04:26

A. I have. 04:26

Q. All right. And it tells you to bring a lot of stuff; right? 04:26

A. Yes. 04:26
Q. So when this is going to be restarted on 04:26
the 18th, there will be a new notice that goes 04:26
out. You will have to bring your stuff and 04:26
somehow the lawyers will figure out a way to get 04:26
this hard drive duplicated so we can find these 04:26
other things; okay? 04:26
A. Okay. 04:26
Q. So it's possible you'll have to be in 04:26
communication with people between now and then -- 04:26
A. Yes. 04:26
Q. -- to facilitate that; all right. 04:26
Okay. Fair enough. 04:27
MR. ANDERTON: We should plan to start 04:27
perhaps as early at 8 o'clock on the 18th? 04:27
THE WITNESS: That's fine. 04:27
BY MR. MORIARTY: 04:27
Q. Let's go to page 8 of your report. Do 04:27
you see in the middle of the page where you have 04:27
the three bullet points? 04:27
A. Yes. 04:27
Q. Does it gives the three addresses? 04:27
A. Yes. 04:27
Q. All right. Do you know that Taft Road 04:27
was only a packaging facility for Digitek? 04:27

A. I knew that it was in limited operations. Specifically packaging, I don't know if I could -- I could say that definitively without going back and looking at the EIR. 04:27

Q. Do you remember anything in a 483 or a warning letter or an EIR to the effect that there was a problem in any facility of Taft Road that affected the potency of Digitek that made it to consumers? 04:27 04:28 04:28 04:28

A. I can't say without going back. It gets pretty complex on what the facilities are and how they are, what's going on at them. It's kind of a mess just breaking out what the three were. So I -- I can't definitively answer that, sorry. 04:28 04:28 04:28 04:28

Q. And do you know what was going on at 990 Riverview Drive? 04:28 04:28

A. Again, it's the same thing. Very confusing reviewing documents what specific operations were going on at these individual facilities. 04:28 04:28 04:28 04:28

Q. Well -- 04:28

A. And how they impacted or didn't. 04:28

Q. Hypothetically I want to you assume that all that was going on at Riverview was -- from a production standpoint was the attempt to validate, 04:28 04:29 04:29

process validate a new location with different equipment to manufacture Digitek; okay? 04:29

A. Theoretically; okay. 04:29

Q. No. 04:29

A. That's what you're saying. 04:29

Q. No, I'm asking you to assume that. 04:29

A. Hypothetically. 04:29

Q. And that no product from Riverview was ever released to market at all; okay. 04:29

A. If that's what you say hypothetically, yeah. 04:29

Q. So if, for example, they had a problem some day with an oil leak on a tableting machine and tablets got oily but were, you know, rejected because they were not going to market anyway, that wouldn't affect the potency of Digitek that actually was made at Little Falls and shipped to consumers, would it? 04:29

A. What facility are we talking about? 04:30

Q. Riverview. 04:30

A. Riverview. Okay. And you're saying that hypothetically if there was problem at Riverview where they're only doing process validation; is that correct? 04:30

Q. Yeah. 04:30

A. That that action would not influence what was going on at the Little Falls facility. Is that what you're saying? 04:30

Q. Yes. 04:30

A. Yes, hypothetically, yes. 04:30

Q. Okay. Well, do you have any evidence that any Digitek that was made at Riverview was released to consumers? 04:30

A. Other than going back and digging through documents, I can't say that explicitly. I -- it's just -- it's too much to go back and piece together. 04:30

Q. Okay. Miss Donahue represents Mylan. Do you know who Mylan is? 04:31

A. I do. 04:31

Q. Do you know that they were only a distributor not a manufacturer of Digitek? 04:31

A. Is that a totally accurate statement because I don't know if I understand the relationship, UDL, Bertek, how they fall into that. 04:31

Q. Do you know whether Digitek was ever manufactured by anyone other than Amide or Actavis? 04:31

A. I don't know that definitively because I 04:31

know there was discussion that Mylan was going to take it over via UDL or Bertek, so I don't know. 04:31

Q. Well, have you seen any documents to indicate that Mylan or UDL ever manufactured tablets of Digitek? 04:31

A. I don't believe that they did. 04:32

MR. MORIARTY: Okay. The bottom line is she has a couple of questions that she wants to get out of the way during session one. So I'm going to let her ask those questions and then if there's time left on my tape, I'll get back to you; okay? 04:32

THE WITNESS: Okay. 04:32

DIRECT EXAMINATION 04:32

BY MS. DONAHUE: 04:32

Q. Good afternoon, Dr. Bliesner. 04:32

A. Hello. 04:32

Q. I have reviewed your -- first, let me start by asking you this. 04:32

A. Yes. 04:32

Q. You are not an expert in pharmaceutical distribution, are you? 04:32

A. Distribution, no. 04:33

Q. And you're not an expert on the industry practices related to pharmaceutical distribution? 04:33

A. Distribution, no. 04:33
Q. You're not expert on the FDA regulations 04:33
applicable to pharmaceutical distribution? 04:33
A. I have not -- I mean don't even know 04:33
what specifically the regulations would relate to 04:33
distribution, so, no. 04:33
Q. So you're not expert? 04:33
A. No. 04:33
Q. And you've never published any articles, 04:33
textbooks, treatises on pharmaceutical 04:33
distribution practices? 04:33
A. I have not. 04:33
Q. Now, I reviewed your 21-plus attachment 04:33
page report before coming here today. 04:33
A. Yes. 04:33
Q. And the purpose of that report is set 04:33
forth on page 1 of your report; correct? 04:33
A. Correct. 04:33
Q. And can you read that purpose out loud, 04:33
please, for the record? 04:34
A. Sure. Purpose: "This report is a 04:34
thorough, detailed, independent review of the 04:34
facts related to Digitek product litigation. In 04:34
particular, this review is specifically conducted 04:34
to determine if Amide Pharmaceutical, Inc. which 04:34

later became Actavis Totowa, LLC and referred to as Amide/Actavis within this report, demonstrated a systematic failure to implement quality systems which in turn created a high likelihood that adulterated product made it to the marketplace." 04:34

Q. Thank you. And is that an accurate statement of the purpose of your report? 04:34

A. Yes. 04:34

Q. And I think you told me -- you told us earlier in response to Mr. Moriarty's questions, that -- let's see. When you first were contacted by Plaintiffs' counsel in these cases, your task or the guidance they gave you was to evaluate the status of Actavis's or Amide's compliance with GMPs; is that correct? 04:34

A. Yes, that's correct. 04:34

Q. If we turn to page -- the bottom of page 20 of your report under the heading root causes for Amide Pharmaceutical and Actavis's failure to comply with GMPs which led to release of adulterated product to market. 04:35

A. Yes. 04:35

Q. You see that there? 04:35

A. I do. 04:35

Q. And then you have list of the root 04:35

causes; right? 04:35
A. Yes. 04:35
Q. And nowhere among the one, two, three, four, five root causes that you've identified in your report is there mention of any conduct on behalf of -- or on the part of Mylan or UDL as a root cause; is that correct? 04:35
A. Specifically, "yes, but." Mylan was contracted to have amide then or Actavis manufacture the tablets, and there was no quality agreement that was in place that I saw in the record. 04:36
So lack of quality assurance oversight overlaps into that because the innovator, as I understand, or the head of the contract -- Mylan in this case as I understand as I read it -- is responsible for the product as well and making sure that their contractors, contract manufacturers, whatever, follow the GMPs. 04:36
Q. Have you been asked in this case by Plaintiffs' counsel to provide an opinion as to Mylan's alleged liability? 04:36
A. Formally, prior to this? 04:36
Q. Yes. 04:36
A. Prior to this session? 04:37

Q. Yes. 04:37
A. No. 04:37
Q. Prior to authoring your report, were you asked by Plaintiffs' counsel to render a report as to Mylan's liability in these cases? 04:37
A. I recall the discussion with the Miller law firm regarding Mylan and asked for guidance. This is from memory, so it's not written down. It's a bit vague. And they -- their guidance was, you know, however they fit into this, put it in your report as you see fit. 04:37
Q. And you saw fit not to mention Mylan specifically or any specific Mylan conduct in the report that you've stated was -- was written for the purpose of advising counsel as to what your opinions are in this case. 04:37
A. There are references in the attachment section to discussions with Mylan that talk about quality issues they were concerned with for some time. 04:38
Q. Okay. Can you please point to me -- 04:38
A. Sure. 04:38
Q. -- in your attachments every reference to Mylan. 04:38
A. Okay. 04:38

MR. MORIARTY: I think this is going to take a couple of minutes. You might want to go off the video record. 04:38

THE VIDEOGRAPHER: The time is 4:41 p.m. We're going off the record briefly. 04:38

(Short break) 04:39

THE VIDEOGRAPHER: The time is now 4:49 p.m. We are back on the record. 04:46

BY MS. DONAHUE: 04:46

Q. All right. Dr. Bliesner, off the record you were reviewing your report -- 04:46

A. Yes. 04:46

Q. -- in order to answer my question which was where -- will you please point out every reference in your report to a Mylan document. 04:46

A. Yes. The other question I have, are you considering UDL Bertek to be part of the Mylan umbrella? 04:46

Q. Sure. 04:47

A. Okay. Page 15, number 33. 04:47

Q. Uh-huh. Yes. Thank you. We have number page 15, number 33? 04:47

A. Yes. 04:47

Q. Yes. 04:47

A. Page 18, number 46. 04:47

Q. Yes. 04:47

A. And number 49. Page 19, number 54. 04:47

Q. Any others? 04:47

A. Yes. Page 41, number A24; page 43, A28; 04:47

page 46, A33; page 47, A36; page 54, A44; page 56 04:48

A 49; page 57 A52; page 58, A53. 04:49

There is a reference to Bertek UDL in A55 on 04:50

page 59, embedded in the press release, and on 04:50

page 60, A59. And I believe with that quick 04:50

review of the report, that should be most all of 04:50

them. 04:50

Q. Thank you. 04:50

A. Uh-huh. 04:50

Q. Now each of those references that you've 04:50

just given us to Mylan documents, are just that; 04:50

correct? They are references to Mylan documents 04:50

and in some instances quotations from the 04:50

documents; is that correct? 04:50

A. For e-mails, yes. 04:50

Q. And nowhere in the course of those 04:50

references have you rendered an opinion in regard 04:50

to Mylan or UDL's conduct in distributing Digitek? 04:50

A. In this report? 04:51

Q. Yes. 04:51

A. I have not written it in the report. I 04:51

do have an opinion, but I have not written it in the report. 04:51

Q. Did you have an understanding as you came here today that your report was to contain the totality of your opinions that you intend to render at trial in this case? 04:51

A. With respect to the guidance that I got, thought and think and do believe that I put the information that was desired specifically related to Digitek, Actavis Totowa. That was my guidance. 04:51

MR. MORIARTY: You have 60 seconds. 04:51

BY MS. DONAHUE: 04:51

Q. As you sit here today, what is your opinion with regard to Mylan's conduct in the distributing Digitek in the case, Mylan and UDL? 04:52

A. Just based upon the documents that I reviewed and, again, not concentrating on Mylan's position in this thing, I found it odd and not customary that no quality agreement was in place. 04:52

Q. You would agree, would you not, that quality agreements are not required by the FDA regulations? 04:52

A. By regulations? Specifically in 21 CFR 210 and 211, not to my knowledge is there a requirement for a quality agreement. It is 04:52

standard industry practice. 04:52

Q. That's a relatively new standard 04:52

industry practice, would you agree with that? 04:52

A. Relatively new? I'm not sure how you 04:52

define relatively new. 04:52

Q. In your opinion, when did it become 04:53

standard industry practice? 04:53

A. Well, let's see. For the last -- at 04:53

least the last three to five years in my 04:53

consulting endeavors I've expected and seen 04:53

quality agreement with contractors. 04:53

Q. Do you understand that as you sit here 04:53

today, Dr. Bliesner, that Mylan or -- neither 04:53

Mylan or UDL was the innovator in regard to 04:53

Digitek? In other words, neither one of them held 04:53

the ANDA? 04:53

A. That is correct. I understand that. 04:53

MS. DONAHUE: Since we're almost out of 04:53

tape, I'm going to stop questioning now, but I 04:53

reserve the right to come back. 04:53

Oh, yeah. Before we go off the record, 04:53

let me finish my sentence. I reserve the 04:53

right to come back and continue my 04:53

questioning. And you've been, I think, taking 04:53

some notes during the deposition and we would 04:53

like to get those marked as an exhibit, please. 04:54

THE WITNESS: Okay. 04:54

MS. DONAHUE: Let's wait. Before we go off the record, let's mark them. 04:54

MR. KERENSKY: You didn't write anything down about Mr. Anderton's tie, did you? 04:54

THE WITNESS: No, it was noted though. 04:54

MR. KERENSKY: Okay. 04:54

MR. ANDERTON: I will accept the compliment. 04:54

(Whereupon, Exhibit 109 was marked for identification) 04:54

THE VIDEOGRAPHER: The time is now 4:57 p.m. We're going off the record. 04:54

(THEREUPON, the taking of the deposition was concluded at 4:57 p.m.)

CERTIFICATE OF OATH

STATE OF FLORIDA

COUNTY OF HILLSBOROUGH

I, the undersigned authority, certify that David Bliesner, Ph.D., personally appeared before me and was duly sworn by me.

WITNESS my hand and official seal, this 3rd day of February, 2011.

_____

PHILIP RYAN, RPR
NOTARY PUBLIC - STATE OF FLORIDA
COMMISSION # DD 988415
MY COMMISSION EXPIRES: JUNE 28, 2014

CERTIFICATE OF REPORTER

STATE OF FLORIDA

COUNTY OF HILLSBOROUGH

I, PHILIP RYAN, RPR, certify that I was authorized to and did stenographically report the foregoing deposition; and that the foregoing transcript is a true record of the testimony given by the witness.

I further certify that I am not a relative, employee, attorney, or counsel of any of the parties, nor am I a relative or employee of any of the parties' attorneys or counsel connected with the action, nor am I financially interested in the action.

DATED this 3rd day of February, 2011.

_____

PHILIP RYAN, RPR

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